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JUL 16 2002

Non-Confidential Summary of Safety and Effectiveness

April 16, 2002

ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Tel (317) 335-3780
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Official Contact: Paul Dryden - President

Proprietary or Trade Name: Infant Feeding Tube

Common/Usual Name: Feeding Tube

Classification Name: Tubes, Gastrointestinal (and Accessories)

Predicate Devices: Vygon – Infant Feeding Tubes – K925854
Klein-Baker – Neo-Care Feeding Tube – K861090
Knott Gastric tube - K971354

Device Description:

The Infant Feeding Tube is a small diameter tube of various sizes - 5,6, and 8 French, and lengths of 14.5", 35" and 41". It has an integral female luer fitting. There are 2 eyelets near the tip of the tube. It has marking along the shaft of the tubing and an integral radiopaque line. It is provided sterile.

Intended Use:

Indicated Use -- The Infant Feeding tube is intended to be placed into the stomach to permit the introduction of fluids as directed by the physician. Intended for nasogastric or orogastric placement. Limited to less than 30 day placement. Not intended for transpyloric placement.

Environment of Use -- Hospital or environment where placement of a feeding tube is required.

K020005

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Comparison to Predicate Devices:

Attribute	Proposed device	Predicate Vygon Infant Feeding Tube - K925854
Intended use		
To be placed into the stomach to permit the introduction of fluids as directed by the physician. Nasogastric or orogastic placement.	Yes	Yes
Intended for single patient use for a duration of < 30 days	Yes	Yes Klein-Baker – Neo-Care Feeding Tube – K861090
Prescription	Yes	Yes
Intended population infants	Yes	Yes
Intended Environment of Use - Hospital or environments where placement of a Feeding tube is required.	Yes	Yes
Design Features		
Provided in various diameters from 4 - 12 Fr	5,6,8 Fr	Yes, 4 – 12 Fr
Standard slip fit female luer connector	Yes	Yes
Two (2) eyelet holes near tip	Yes	Yes
Radiopaque line entire length of tubing	Yes	Yes
Markings along the length of the tubing	Yes	Yes
Materials		
Tubing and Connector - PVC	Yes	Yes- Knott Gastric tube - K971354
Packaging		
Sterile	Yes	Yes
Performance		
None under Section 514	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicate – Vygon Infant Feeding Tube – K925854, Knott Gastric tube - K971354, and Klein-Baker – Neo-Care Feeding Tube – K861090.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Mr. Paul Dryden
President
ProMedic, Inc.
6329 W. Waterview Ct.
MCCORDSVILLE IN 46055

Re: K020005
Trade/Device Name: Infant Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: April 16, 2002
Received: April 17, 2002

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K020005 (To be assigned)

Device Name: Infant Feeding Tube

Intended Use: The Infant Feeding tube is intended to be placed into the stomach to permit the introduction of fluids as directed by the physician. Intended for nasogastric or orogastric placement. Limited to less than 30-day placement. Not intended for transpyloric placement.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _XX__ **or** **Over-the-counter use __**
(Per CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020005